UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,692	12/11/2003	Philip Stashenko	25669-003	4324

7590 03/01/2010

Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
03/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,692	STASHENKO ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,27-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,27-29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 12/09/2009 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claim 1 and the cancellation of claim 26 have been made of record.

Claims1, 27-29 and 31-33 are pending and under examination.

Response to Arguments

Claim Objections-*withdrawn*

The objection of claim 1 for missing an article before the term "activity" is withdrawn in view of applicants' amendment to claim 1 filed on 12/9/09.

Claim Rejections *- maintained*

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 27-29 and 31-33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record in pg. 3-7 of the Office Action of 7/09/2007 and in pg. 2-4 of the Office Action of 6/9/2009 and as discussed below.

2. Claims 1, 27-29 and 31-33 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that could bind to a protein encoded by a product of OC14 gene, does not reasonably provide

enablement for a method of inhibiting osteoclast-mediated bone resorption comprising inhibiting an activity of a gene product encoded by OC14 gene by administering any antisense polynucleotide or any antibody that inhibits said activity by inhibiting the expression of said gene product for the reasons of record in pg. 4-8 of the office action of 6/9/2009 and as discussed below.

Applicants argue (pg. 4-5 of Response) that claim 1 is amended to recite methods of inhibiting osteoclast-mediated bone resorption by administering a compound that inhibits the activity of a gene product encoded by OC14, wherein the activity is inhibited by administering a compound that inhibits the expression of said gene product and wherein said compound is an antibody or an antisense polynucleotide. Applicants reiterate their arguments that the instant invention is not limited to a specific compound and argue that the invention is drawn to a method of inhibiting osteoclast-mediated bone resorption by inhibiting the expression of OC14 gene. Applicants argue (pg. 5 of Response) that the claimed method is described throughout the specification, e.g., at pages 1-2, and 49. They argue that a previously presented, post-filing art by two of the inventors (Battaglino and Stashenko, Bone, vol 42, 180-192, 2008) show that siRNA against OC-14 inhibits osteoclast differentiation and resorption.

Applicants' arguments have been fully considered but they are not persuasive because the specification does not disclose any antibody or any antisense nucleic acid that inhibits osteoclast-mediated bone resorption. The instant claims are broadly drawn a method of inhibiting osteoclast-mediated bone resorption comprising administering a compound that inhibits activity of a gene product of OC14. The specification on pages

1-2, and 49 discloses, in general, how one of the skill in the art could use an antibody to inhibit a protein activity, or page 61 of the specification discloses using antisense polynucleotide to inhibit gene expression, wherein said inhibition can be at least 10%, 20%.....or at least 90% in a cell based assay. But the specification does not disclose any antibody or any antisense polynucleotide, which when administered to a subject or model inhibits said activity of OC14 of SEQ ID NO: 50 at least 10% and results in osteoclast-mediated bone resorption. Applicants' arguments that the instant invention is drawn to a method of inhibiting osteoclast-mediated bone resorption by inhibiting the expression of OC14 gene have been fully considered but they are not persuasive because the method is broadly drawn to inhibiting osteoclast-mediated bone resorption which is achieved by administering an antibody or an antisense polynucleotide encompasses bone resorption in a subject. Therefore, one of the skill in the art has to identify an antibody or an antisense polynucleotide that inhibits activity of a gene product encoded by OC14 and then has to administer such a compound to find out if said can inhibit osteoclast-mediated bone resorption. The specification fails to disclose any compound which inhibits said activity of OC14 of SEQ ID NO: 50 at least 10% that results in osteoclast-mediated bone resorption. Regarding applicants' arguments that the reference Battaglino et al teaches that a siRNA against the OC-14 gene can inhibit osteoclast differentiation and resorption have been fully considered and they are found persuasive but the claims are not drawn to a method of inhibiting bone resorption in vitro by administering a siRNA against the OC14 gene. It is noted to Applicants that the office record does not show that this reference was previously made available to the

office as argued in the Response filed on 12/9/2009. Applicants should provide a specific date when the reference was provided to the office in order to make the record clear. The instant invention is broadly drawn to a method of inhibiting osteoclast-mediated bone resorption by administering an antisense polynucleotide or an antibody which includes in vivo treatment (in a subject). Neither the art nor the instant specification teaches any antisense polynucleotide or any antibody which results in osteoclast-mediated bone resorption in a subject. It is noted to applicants that if claims are amended to inhibiting osteoclast resorption in a bone cell (RAW 264.7) by administering an antibody will be considered favorably. Therefore, the rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
AU 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647